

Remarks

Claims 1-19 were pending. Claims 7 and 9 are withdrawn from consideration. Claims 2 and 10 - 18 are canceled. Claim 1 is currently amended. No new matter is added. Applicants respectfully request reconsideration of the rejections.

The claims as currently amended cover methods for removing or repositioning lower GI stents used to alleviate malignant bowel obstruction.

All pending claims have been rejected under 35 U.S.C 103(a) as being unpatentable over Uflacker (5,776,186) in view of Cox et al (US 5,290,294). The Office Action states that Uflacker teaches a woven wire mesh self expanding luminal stent comprising a closed loop of high strength material through one or both termini of the stent, which can thus be repositioned.

It is noted by the Examiner that Uflacker does not teach the use of the stent in the gastrointestinal tract, or for malignant bowel obstruction, nor does the reference teach the grasping device comprising two or more hinged elements.

Applicants respectfully submit that the presently claimed method is not taught or suggested by the cited combination of references. Uflacker teaches a graft that can be repositioned, not a stent. It is known in the art that for certain purposes, such as an aneurism (see Uflacker, summary of the invention, 2:32-33) one may desire to introduce a graft. Such a graft is typically a flexible mesh, such as a PTFE fabric, or a similarly soft and flexible wire mesh. As discussed in Uflacker, the graft is used to re-line a path where the lumen of the vessel has distended out (1:26-28). Such grafts typically are very flexible, and do not have a supporting function, hence they are often used in combination with a stent.

Uflacker, therefore, does not teach the use of the tightening loop with a stent, but rather the use of such a loop with a graft (as noted by the Examiner, the paragraph at 3:60-67 specifically teaches a polyester fabric graft). This is an important distinction because the graft does not have the supporting function that a stent does. While one of skill in the art would naturally expect a graft to be readily collapsible, the same is not true of a stent, which must have a supporting role.

This distinction is particularly important when the use of the stent is for an obstruction, not an aneurism. In treating an obstruction, the structural integrity of the stent is critical. One

could not imagine that a polyester fabric or wire mesh suitable for a graft could also be used in place of stent for these indications.

The secondary reference, Cox, fails to remedy the deficiencies of the primary reference. While Cox teaches a grasping device for the non-surgical removal of foreign bodies, the combination of reference fails to suggest a method for the repositioning or removal of a luminal stent from the gastrointestinal tract, wherein the stent is used to alleviate malignant bowel obstruction.

Uflacker teaches the repositioning of a fabric graft, while Cox teaches the removal of foreign bodies from a body cavity. The two references fail to provide key elements of the claimed invention.

To improve the treatment of MBO, several groups have begun using expandable stents to mechanically relieve the obstruction (Soetikno et al, 1999; Gastrointest. Endosc. Clin. Of North Amer., 9(3):447-458). The preliminary results using expandable stents have been promising, but there are significant problems that must be overcome. Most significant is that the stents as currently designed and used are not suitable for long-term use (i.e. > 1 year). With time, the stents can become clogged with debris, move from their initial position, or lead to hyperplastic growth of the surrounding tissue. Because the patients in which the stents have been used do not have long life expectancies, this drawback was not a top concern. However, there are many patients in need of this treatment whose life-expectancy is significantly longer, including those in which the bowel obstruction is not caused by malignancy.

Without a doubt, the usefulness of lower GI stents would be significantly enhanced if there were a method to efficiently and non-surgically reposition or remove them. Such a method would enhance the efficacy, safety, and functionality of lower GI stents thereby expanding the patient pool eligible for this treatment and meeting a significant unmet medical need. The present application discloses such a method, and will provide significant benefit to patients over current medical practice. As such, Applicants argue that the methods described in the presently amended claims constitute patentable matter.

In view of the above amendments and remarks, withdrawal of the rejection is requested.

CONCLUSION

In view of the above amendments and remarks, this application is considered to be in good and proper form for allowance and the Examiner is respectfully requested to pass this application to issuance.

The Commissioner is hereby authorized to charge any underpayment of fees associated with this communication, including any necessary fees for extensions of time, or credit any overpayment to Deposit Account No. 50-0815, order number STAN-219.

Respectfully submitted,
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